

**IN THE UNITED STATES DISTRICT COURT FOR THE
NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION**

JANE DOE,

Plaintiff,

V.

BLUE CROSS BLUE SHIELD
HEALTHCARE PLAN OF GEORGIA,
INC.,

Defendant.

Civil Action File No.
CaseNumber

COMPLAINT

COMES NOW Plaintiff, Jane Doe (“Doe”), and files this Complaint against Defendant the Blue Cross Blue Shield Healthcare Plan of Georgia, Inc. (“Blue Cross”), showing the Court as follows:

PRELIMINARY ALLEGATIONS

1.

This action is brought under 29 U.S.C. §§ 1132(a), (e), (f) and (g) of the Employee Retirement Income Security Act of 1974 (hereinafter “ERISA”) as it involves a claim by Plaintiff for employee benefits under an employee benefit plan regulated and governed under ERISA. Jurisdiction is predicated under these code sections as well as 28 U.S.C. § 1331 as this action involves a federal question. This action is brought for the purpose of obtaining benefits under the terms of an

employee benefit plan and enforcing Plaintiff's rights under the terms of an employee benefit plan. Plaintiff seeks relief, including but not limited to: health coverage under the Plan, approval and payment of benefits for healthcare expenses incurred due to denial of health coverage under the Plan, prejudgment and post-judgment interest, and attorneys' fees and costs.

JURISDICTION AND PARTIES

2.

The "Plan" is an employee welfare benefit plan as defined by ERISA, 29 U.S.C. § 1002(1).

3.

Jurisdiction is based on ERISA, 29 U.S.C. § 1132(e)(1) and 28 U.S.C. § 1331.

4.

Venue is proper in the United States District Court for the Northern District of Georgia pursuant to 29 U.S.C. § 1132(e)(2) because the breach of Blue Cross's duties alleged herein occurred in this district and Plaintiff lives in this district.

5.

Defendant Blue Cross is a Georgia corporation that conducts business in the State of Georgia.

6.

This Court has personal jurisdiction over Defendant.

7.

Defendant Blue Cross may be served through its registered agent for service, CT Corporation System, located at 410 Peachtree Parkway Suite 4245, Cumming, GA, 30041.

8.

Jane Doe is a “participant” in the Plan, as defined by ERISA, 29 U.S.C. § 1002(7) pursuant to which she and her dependent minor daughter M.Z.¹ are entitled to health benefits.

9.

The Plan is a multiple employer welfare arrangement governed by ERISA and administered by Blue Cross.

10.

Blue Cross made all decisions concerning Plaintiff’s claim for benefits under the Plan and handled all communications concerning Plaintiff’s claim and appeal.

¹ Plaintiff’s minor daughter is referenced only by her initials pursuant to Federal Rules of Civil Procedure 5.2. Plaintiff proceeds with a pseudonym in litigation to further comply with Rule 5.2 in protecting her child’s identity from disclosure in this public filing.

FIRST CLAIM FOR RELIEF

DENIAL OF PLAN BENEFITS

11.

Plaintiff requests Blue Cross approve and pay benefits for her daughter M.Z.'s treatment with IVIg infusions of Octagam.

M.Z.'s Diagnosis of PANDAS

12.

M.Z. is a seven year old with a diagnosis of Pediatric Autoimmune Neuropsychiatric Disorder Associated with Streptococcal Infections (PANDAS).

13.

PANDAS is a neuropsychiatric disease with acute onset of neuropsychiatric symptoms such as tics. PANDAS patients test positive for a recent streptococcal infection, such as strep throat. These infections can cross the blood brain barrier and cause an inflammatory response in the basal ganglia. Following infection with strep, children with PANDAS syndrome develop severe physical, neurological, and psychological symptoms that interfere with their daily lives. PANDAS can become chronic or life-threatening if untreated.

14.

M.Z. developed PANDAS in 2022. She had strep infections followed by abrupt changes in behavior which included aggression towards other children and her mother, paranoia, emotional outbursts, fever, headache, gastrointestinal pain, anxiety, crying, hiding, running away, throwing things, and hitting/pinching/biting people.

15.

As her strep infections became more frequent, her symptoms worsened. She had tantrums as frequent as daily, sleep difficulty, urges to vomit, and developed tics.

16.

She started school and had several episodes of behavioral dysregulation and aggression towards children which led to her presenting to the emergency department for an inpatient evaluation with a neurologist in August 2023.

IVIg Treatment for Patients Diagnosed with PANDAS

17.

Intravenous immunoglobulin (IVIg) is a standard of care for patients diagnosed with PANDAS.

18.

More than ten states (including Arkansas, Delaware, Illinois, Indiana, Maryland, Minnesota, New Hampshire, Oregon) have passed laws requiring health plans and/or health insurance companies cover the treatment of PANDAs, including IVIg treatment. A bill was introduced by the General Assembly in Georgia to require coverage for treatment of PANDAS.

19.

Blue Cross insures and/or administers plans providing coverage for treatment of PANDAs, including IVIg treatment. For example, Blue Cross issues health plans in Indiana which provide coverage for IVIg treatment for patients diagnosed with PANDAS:

Pediatric Neuropsychiatric Disorders

This Plan provides coverage for treatment of Pediatric Neuropsychiatric Disorders for pediatric autoimmune neuropsychiatric disorders associated with streptococcal infections (PANDAS); and pediatric acute-onset neuropsychiatric syndrome (PANS) including treatment with intravenous immunoglobulin therapy. Coverage will not be subject to dollar limits, Deductibles, Copayment or Coinsurance that are less favorable than the dollar limits, Deductibles, Copayments or Coinsurance provisions that apply to other coverage under Your Plan.²

² *i.e.* <https://www.chem.indiana.edu/wp-content/uploads/2022/08/ga-medical-booklet.pdf> at p. 52; <https://eoc.anthem.com/eocdps/9Q1KIND01012024> at p. 43.

Plaintiff's Claims and Appeals for M.Z.'s IVIg Treatment

19.

The Plan provides coverage for medically necessary healthcare services for treatment of an illness.

20.

The Plan defines medically necessary, in pertinent part, as services: “appropriate and consistent with the diagnosis and the omission of which could adversely affect or fail to improve the patient’s condition; compatible with the standards of acceptable medical practice in the United States. . .”

21.

In February 2024, M.Z.’s provider requested authorization from Blue Cross for M.Z. to receive infusions of IVIg Octagam once every four weeks, split over two days.

22.

In a letter dated March 21, 2024, Blue Cross denied the request for authorization, claiming that it only approved Octagam for certain conditions and uses and M.Z. did not have any of the listed conditions or intended uses. Blue Cross did not address M.Z.’s diagnosis of PANDAS.

23.

On April 2, 2024, M.Z.'s pediatrician, Dr. Eve Wexler, appealed the denial and explained that Octagam is the standard of care for treatment of patients diagnosed with PANDAS.

24.

Dr. Wexler wrote that M.Z. tried and failed to achieve a sustained clinical response to treatment with antibiotics, Zolo, Celebrex, nystatin, Risperda, Pepcid, and other supplements.

25.

Dr. Wexler wrote that M.Z. showed clinically significant improvement with her first dose of Octagam.

26.

Dr. Wexler wrote that Octagam is supported as standard of care for treatment of patients diagnosed with PANDAS:

[T]here is current evidence that IVIg can be a safe and effective therapy for autoimmune and inflammatory conditions including autoimmune encephalitis and PANS/PANDAS, especially when refractory to standard therapies. **Its use is widely accepted as standard medical practice.** Autoimmune neurologic disorders are diverse and evidence from randomized controlled trials is limited for most of the immunotherapies used in neurology. Providers must use the most current available evidence when deciding on a treatment option. It is

common practice for IVIg to be ordered when symptoms are progressive, severe and other treatments have failed. [M.Z.] has tried and failed multiple other treatments so far, however her debilitating symptoms have proven responsive to treatment with IVIg. Therefore, based on the dramatic clinical improvement [with] IVIg, I have ordered the continuation of Octagam 50gms IV every 4 weeks as medically necessary. This request is evidence based and in accordance with the course of treatment in the following references provided.

(Emphasis added).

27.

Dr. Wexler provided citations to several studies supporting the medical necessity of Octagam for M.Z., including findings that IVIg is the preferred treatment for PANDAs patients.

28.

Dr. Wexler further wrote:

Immunoglobulin therapy is widely accepted by medical experts as a viable treatment option for autoimmune conditions. Studies have shown IVIg to be a safe and effective treatment option for immune mediated neurological and psychiatric disorders. IVIg is standard of care and considered a first line treatment for autoimmune encephalitis. It has been shown to be effective in both adults and children in medical literature and therefore is not considered experimental/investigation. Given that Max has shown previous improvement on IVIg and that autoimmune encephalitis can lead to morbidity and mortality, it is medically necessary for Max to continue to receive treatment with IVIg.

29.

In a letter dated April 30, 2024, Blue Cross denied the appeal, claiming Octagam was not medically necessary and “Your condition is not one that can be approved under the criteria because there is no proof, or not enough proof that it improves health.”

30.

Blue Cross did not address, acknowledge, or refute the opinion or appeal letter of Dr. Wexler or any of the medical studies cited with the appeal.

31.

Defendant wrongly denied benefits for IVIg infusion of Octagam for M.Z. in the following respects, among others:

- (a) Failure to authorize and pay for health benefits as required by the Plan at a time when Defendant knew Plaintiff was entitled to such benefits under the terms of the Plan;
- (b) Failure to provide reasonable explanations of the bases relied on under the terms of the Plan, in relation to the applicable facts and plan provisions, for the denial of claims for health benefits;
- (c) After claims were denied in whole or in part, failure to adequately describe to Plaintiff any additional material or information necessary to

perfect her request along with an explanation of why such material is or was necessary;

- (d) Failure to properly investigate the merits of the request and appeal submission; and
- (e) Failure to provide Plaintiff with a full and fair review pursuant to 29 C.F.R. § 2560.501-1 (h)(3)(iii) by failing to consult with health care professionals who have appropriate training and experience in the field of medicine involved in the medical judgment.

32.

Plaintiff is informed and believes and thereon alleges that Defendant wrongfully denied medical benefits by other acts or omissions of which Plaintiff is presently unaware, but which may be discovered in this future litigation and which Plaintiff will immediately make Defendant aware of once said acts or omissions are discovered by Plaintiff.

33.

Following the denial of the request for benefits under the Plan, Plaintiff exhausted all administrative remedies required under ERISA, and performed all duties and obligations on her part to be performed.

34.

Plaintiff seeks to recover benefits due to her under the terms of the Plan and to enforce her rights under the plan pursuant to 29 U.S.C. § 1132(a)(1)(3).

35.

As a proximate result of the denial of medical benefits, Plaintiff has been damaged by the cost of IVIg infusions, in the approximate amount of \$25,000.00, and requests ongoing IVIg infusions for M.Z. in accordance with her physicians' recommendations, with the total sum to be proven at the time of trial.

36.

As a further direct and proximate result of this improper determination regarding the medical claims, Plaintiff, in pursuing this action, has been required to incur attorneys' costs and fees. Pursuant to 29 U.S.C. § 1132(g)(1), Plaintiff is entitled to have such fees and costs paid by Defendant.

37.

Due to the wrongful conduct of Defendant, Plaintiff is entitled to enforce her rights under the terms of the Plan and to clarify her rights to future benefits under the terms of the Plan.

REQUEST FOR RELIEF

Plaintiff requests judgment against Defendant as follows:

1. Payment of medical benefits due to Plaintiff under the Plan;
2. Ongoing approval of IVIg infusions of Octagam for M.Z. in accordance with continued recommendation from her treating physicians;
3. Pursuant to 29 U.S.C. § 1132(g), payment of all costs and attorneys' fees incurred in pursuing this action;
4. Payment of prejudgment and post judgment interest; and
5. For such other and further relief as the Court deems just and proper.

Respectfully submitted, this 3rd day of July, 2024.

EVANS WARNCKE ROBINSON, LLC

By: /s/ Steven J. Mitchell

Steven J. Mitchell
Georgia Bar No. 669018

Attorney for Plaintiff
6075 Barfield Road, Ste. 1200
Atlanta, GA 30328-4402
P: 404.841.9400
F: 678.904.6851
E: s.mitchell@ewrlawfirm.com